

Attorney Docket No. 8964-000019/US
Application No. 10/629,212

REMARKS

Favorable reconsideration of this application in light of the following remarks is respectfully requested.

No claims having been cancelled or added, the Applicants respectfully submit that claims 2-14 remain pending in the present application and remain properly under consideration with claims 2, 10 and 11 being presented in independent form.

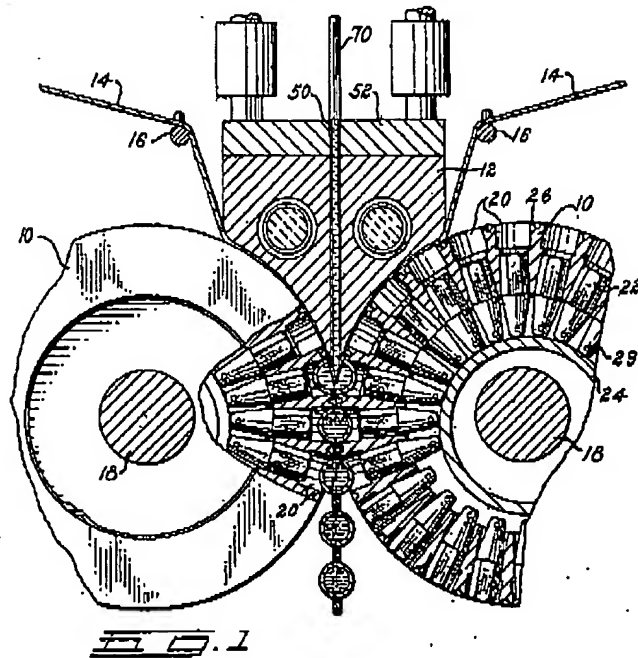
Rejections under 35 U.S.C. § 103

Claims 2-14 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Haman et al.'s U.S. Patent No. 4,656,092 ("Haman") in view of Brox et al.'s U.S. Patent No. 6,589,536 ("Brox") and Stolz U.S. Patent No. 6,530,962 ("Stolz"). The Applicants respectfully traverse this rejection for the reasons detailed below.

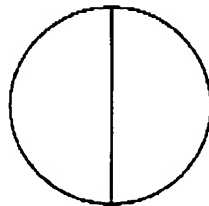
The Applicants maintain that, contrary to the representation in Haman, col. 2, lines 45-49, and the Action at 2, the "soft gelatin capsule shell" as taught in Haman cannot be considered *seamless*. The Applicants note that the plain meaning of "seam" is a line of junction, ridge or groove formed by fitting or joining together two sections along their edges. Webster's New Riverside University Dictionary, p. 1052 (1988).

The Applicants maintain that Haman incorporates certain U.S. patents by reference in lieu of providing specific disclosure regarding the production of the capsule shell. Haman, col. 2, lines 62-66. As reflected in the most recent of the incorporated patents, U.S. Patent No. 2,318,718 ("the 718 patent") to Scherer, manufacturing the capsules involves bringing together two separate gelatin layers 14 between two die rolls

during which the capsule is formed, filled and sealed. Figure 1 of the '718 patent, reproduced below, illustrates Scherer's method.



The formed capsules are then cut from the sheet to obtain the individual capsules. Thus the only method taught or suggested by Haman involves joining two separate sheets of material in a manner that will inevitably produce at least an equatorial "seam," as illustrated below, at which the two sheets are joined.



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The Applicants contend, therefore, that the continued reliance on Haman's characterization of the resulting paintballs as "seamless" is unwarranted in the face of direct evidence in Haman's disclosure to the contrary. The Applicants contend that this reliance, while convenient, is not supported by a "convincing line of reasoning" as to why one skilled in the art would reject the plain teaching of Haman's disclosure in order to conclude that Haman's paintball is truly seamless. *Ex parte Clapp*, 227 USPQ 972, 973 (B.P.A.I. 1985). The Applicants contend that such unwarranted reliance on an unsupported and inconsistent characterization of the nature of a product could be used to maintain that the prior art also taught paintballs that are "weightless" and/or "frictionless" if the patentee had been brazen enough to make such a claim.

The Applicants note that Brox, like Haman, provides only for the production of seamed capsules resulting from the joining of two separate gelatin bands. Specifically, Brox teaches:

The process according to the invention is basically carried out in the same manner as usual in accordance with the *Rotary Die Process* as described in greater detail, inter alia, in Lachmann et al., "The Theory and Practice of Industrial Pharmacy", 2nd Edition, pages 404-419. It is apparent from FIG. 13-9 and its description in page 414, right column, last paragraph, that the *gelatin band* is passed over an air-dried rotating drum. The temperature of the cold air was reported to be 56° F. to 58° F., corresponding to 13.3° C. to 14.4° C., but this only inefficiently cools the gelatine.

Brox, col. 6, lines 13-21 (emphasis added). Indeed, the Brox disclosure is focused in large part on methods for reducing the "tackiness" of the PEG-containing gelatin bands as they pass over the rotary dies and are pressed together to join portions of the bands along a seam as the capsules are formed. Thus, Brox does not remedy the deficiencies of

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Haman with respect to the formation of seamless paintballs. Further, the Applicants submit that teachings with respect to the compositions of solid gelatin bands used in the rotary die processes of Haman and Brox cannot fairly be extrapolated to the compositions suitable for forming the claimed seamless paintballs in a liquid encapsulation process absent some additional technical or logical basis for making such a conceptual leap. *Ex parte Clapp*, 227 USPQ 972, 973 (B.P.A.I. 1985).

The Applicants also note that Brox teaches adding PEG to the shell composition in order to compensate for migration of PEG from the fill materials. Indeed, Brox specifically provides that:

Since propyleneglycol, and more specifically 1,2-propyleneglycol, is a good hydrophilic solvent, *it would be desirable to employ this solvent also for the preparation of capsule fillings*. It is true, it is readily possible to produce such gelatin capsules wherein, for example, glycerol or sorbitol are used as the plasticizer for the capsule shell. However, such soft gelatin capsules are not stable, since with the lapse of time *the propyleneglycol migrates into the capsule shell from the capsule filling so that the capsules will become weak*.

Furthermore, such softened capsules will undergo deformation, because due to the migration of part of the solvent into the capsule shell from the capsule filling there will be a decrease in volume and a reduction in pressure in the interior of the capsule.

We have now found that *the migration of, e.g. 1,2-propyleneglycol, may be hindered by using this component in the gelatine band composition* with the result that it is present in the capsule shell. However *we also experienced difficulties in the commercial manufacture of soft gelatine capsules containing 1,2, propylene glycol*.

Brox, col. 2, lines 5-23 (emphasis added).

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Accordingly, one skilled in the art relying on Brox would not be motivated to add PEG to the shell composition, and endure the attendant processing complications, unless the fill material also included PEG. Indeed, Brox further provides:

Typical migrateable solvents include tetrahydrofuryl alcohol ethers, e.g. glycofurol diethylene glycol mono ethyl ether, e.g. transcutool, 1,3-dimethyl-2-imidazolidinone, dimethylisobornide, polyethylene glycol (e.g. of molecular weight from 200 to 600) and preferably propylene glycol or solvents having similar migration capability. *Preferably, the concentration of the migrateable component in the capsule shell is chosen to be so high that an approximately stable equilibrium of the concentrations between the capsule shell and the capsule filling is established soon after encapsulation. During the equilibration phase the migrateable component may migrate from the capsule shell into the capsule filling (thereby increasing its concentration in the capsule filling and decreasing it in the gelatine shell), but migration of the migrateable component into the capsule shell from the capsule filling is significantly reduced.*

Brox, col. 3, lines 45-60 (emphasis added).

The Applicants note, however, that the fill material used in the claimed paintballs is "an oil-based solution including 1%-5% (W/W) edible dye in edible oil" and does not include one of Brox's identified "migrateable" compounds. The Applicants also note that Haman's recommended fill materials do not include any PEG. Accordingly, the Applicants contend that none of the "advantages" touted by Brox would be realized by modifying the Haman shell material to incorporate the PEG and that one skilled in the art would not, therefore, be motivated to make such a combination.

The Applicants further contend that a conclusory allegation regarding PEG's well known physical characteristics is inconsistent with the plain teaching of Brox with respect to the processing complications associated with the addition of PEG. Accordingly, the Applicants maintain that one skilled in the art, relying on the applied

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references, would conclude that adding PEG to a shell composition would be detrimental absent PEG in the fill material and would not be motivated to make the proposed combination as suggested by the Examiner.

Like Haman and Brox, the Applicants note that the only production technique taught or suggested in Stolz involves the use of conventional die rolls into which solid casing materials are fed to produce, inevitably, *seamed* capsules. Stolz provides:

The impact-rupturable capsules of the invention can be prepared using conventional techniques and apparatuses. Generally, with some modifications, the apparatuses used to prepare soft gelatin capsules in the pharmaceutical field can be used to manufacture impact-rupturable capsules. One example of a suitable apparatus is described in Stroud et al. U.S. Pat. No. 5,735,105, the entire text of which is incorporated herein by reference. This patent describes an apparatus and method for preparing liquid-filled capsules using a *die roll apparatus* through which a casing material in the form of a *ribbon or sheet* is fed.

Stolz, col. 6, lines 14-24 (emphasis added).

Stolz also provides some generic disclosure regarding possible components for shell compositions that would be compatible with "conventional die roll encapsulation manufacturing techniques." Stolz, col. 5, lines 48-49. Stolz' ruminations on shell materials provides:

Even more preferred are casing materials which can be formed into an [sic] elastic ribbons or sheets to be filled with liquid and are suitable for heat or solvent sealing consistent with conventional die roll encapsulation manufacturing techniques. Additional suitable casing materials include, but are not limited to, gelatin, PVC, celluloses, modified starches, carrageenans, gums, pectins, alginates, and the like. Those skilled in the encapsulation arts will readily be able to select the appropriate casing material based upon the composition of the fill and the equipment used to perform the encapsulation. Generally, the casing material used for the

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capsule is any material usually used for the shell of a soft capsules. An example of a useful casing material is one consisting primarily of gelatin and further containing a plasticizer, pigment, solubility adjusting agent, and the like.

Stolz, col. 5, lines 46-61.

The Applicants contend that Stolz, while suggesting a wide range of possible materials, does not provide any specific teaching sufficient to lead one skilled in the art to "include starches and dyes in the shell of Haman." Action at 2. Indeed, the Applicants suggest that one skilled in the art would understand the cited passage to be suggesting that "modified starches," along with PVC, celluloses, etc., are alternatives to, rather than additives for, the basic gelatin shells of Haman.

The Applicants further contend that a conclusory allegation regarding "those materials' well known physical characteristics" is insufficient to compensate for the very general teaching of Stolz. The Applicants submit that some additional technical or logical basis upon which one skilled in the art could correlate some expected or reasonably anticipated "advantage" to the proposed modification(s) is necessary for this rejection to be properly supported.

The Applicants also note that Stolz is directed to the use of water soluble dyes in a non-aqueous (lipophilic carrier) that require the use of substantial quantities of one or more emulsifiers and, typically, additional thickening agents, to provide a fill composition exhibiting both increased viscosity and improved washability. The fill material of the claimed paint balls, however, is an "oil solution" rather than an emulsion and does not, therefore, include or require an emulsifier.

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As made clear in Brox and discussed above, the composition of the shell is, in many respects, determined by the nature of the fill composition that it will encompass and the storage life and dimensional stability necessary for the intended use. The Applicants contend, therefore, that the fundamentally different fill material utilized by Stolz would tend to discourage one skilled in the art from utilizing Stolz' cursory discussion of the shell materials with any reasonable expectation of success for fill materials that are not lipophilic emulsion including up to 25 wt% emulsifier. Stolz, col. 4, lines 9-17.

The Applicants request, therefore, that these rejections be reconsidered and withdrawn.

With regard to the various dimensions and ratios recited in the dependent claims, the Applicants contend the absence of any identified teaching or suggestion with respect to the claimed seamless paintballs precludes one of ordinary skill from conducting any "routine experimentation" from the starting point provided by the applied references and thereby achieving the claimed invention or any of the embodiments encompassed by the dependent claims. The Applicants also note that only "result-effective" parameters, *i.e.*, those parameters which correlate to a recognized result, may be optimized through "routine experimentation." *In re Antonie*, 559 F.2d 618 (CCPA 1977). The Applicants submit, therefore, that because no evidence has been identified as relating to seamless paintballs or any guidance regarding the selection and/or blending of PEG components in the shells of such seamless paintballs, the selection of the PEG component of the shell

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cannot fairly be characterized as “result-effective” parameter or variable on the present record. The Applicants, therefore, maintain that the application of the “routine experimentation” rationale, Action at 3, to remedy the deficiencies of the applied references is improper absent a showing that the parameters to be “optimized” were previously recognized as “result-effective” parameters in seamless paintballs.

Further, the Applicants contend that while there is some overlap of the molecular weight ranges provided in Brox’s claim 2, “a [PEG] molecular weight of 200 to 600,” Action at 3, and the 200-6000 dalton range of claim 6 and the 400-6000 dalton range of claim 8, the Applicants maintain that no teaching or suggestion has been identified to suggest that ranges of PEG used in preformed sheets of casing materials are in any way applicable to the ranges of PEG used in seamless paintball casings formed directly from an aqueous solution.

The Applicants request, therefore, that these rejections be reconsidered and withdrawn.

Comments on Response to Arguments

As discussed above, whether or not Haman was “explicit” in characterizing his paintball as “seamless,” Action at 3, the *only* production method taught or suggested by Haman is *incapable* of making a paintball that does not include a seam. Accordingly, Haman cannot fairly be said to teach or suggest a paintball that is “seamless,” *i.e.*, does

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not include a seam. To the extent that Haman may have been using "seamless" in a manner intended to exclude only certain types of seams, *e.g.*, a ridge, that could be achieved by subsequent treatment of the paintball, such a use does not exclude the continued presence of a "seam" within the plain and ordinary meaning of the term. The Applicants maintain, therefore, that neither Haman nor the other applied references can fairly be said to teach or suggest a "seamless paintball."

With regard to the Examiner's contentions regarding a "difference in degree," Action at 4, the Applicants contend that as used in the present application the term "seamless" is limited to those structures which do not include any seams. Accordingly, any paintball that includes a seam of any kind, whether that seam is internal, external, raised or recessed, is not "seamless." Again, as detailed in the Remarks provided above, each of the applied references are clearly and unequivocally directed to means of capsule production that will inevitably produce "seamed" capsules. The Applicants maintain, therefore, that no teaching has yet been identified that can fairly be said to render the claimed "seamless paintballs" obvious.

CONCLUSION

In view of the above remarks, the Applicants respectfully submit that each of the pending rejections has been addressed and overcome, leaving the present application in condition for allowance. A notice to that effect is respectfully requested.

If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

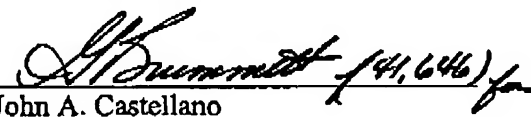
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If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge any underpayment or non-payment of any fees required under 37 C.F.R. §§ 1.16 or 1.17, or credit any overpayment of such fees, to Deposit Account No. 08-0750, including, in particular, extension of time fees.

Respectfully submitted,

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